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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,057	09/22/2003	Anthony D. Sandler	17023-032US1	7283

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EXAMINER
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HUFF, SHEELA JITENDRA

ART UNIT	PAPER NUMBER
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1643

DATE MAILED: 12/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/668,057

Applicant(s)

SANDLER, ANTHONY D.

Examiner

Sheela J. Huff

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-19, 22 and 23 is/are pending in the application.
- 4a) Of the above claim(s) 19 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-18 and 22 is/are rejected.
- 7) ☒ Claim(s) 6 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***DETAILED ACTION***

***Response to Amendment***

The amendment filed on 10/27/06 has been considered. Applicant's arguments are deemed to be persuasive-in-part.

Claims 1-19 and 22-23 are pending.

The rejection under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicant's amendment.

The rejection under 35 U.S.C. 112, first paragraph, (written description) is withdrawn in view of applicant's amendment.

The art rejection is withdrawn in view of applicant's arguments.

The objection to the specification is withdrawn in view of applicant's amendments.

***Election/Restrictions***

Newly submitted claim 23 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the reasons set forth in the restriction requirement mailed 2/23/06.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 19 (which was withdrawn from consideration in the previous action) and claim 23 (which is currently withdrawn) are both withdrawn from consideration.

Claims 1-18 are currently under consideration.

***Response to Arguments***

***Claim Rejections - 35 USC § 112***

Claims 1-5, 7-18 remain and 22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a diagnostic method for predicting the recurrence of a tumor or cancer in a human by quantifying the amount of surviving protein, does not reasonably provide enablement for a diagnostic method for predicting the recurrence of a tumor or cancer in any mammal by calculating the protein ratio of surviving to PAF wherein the ratio more than about 1.5 is predictive that the tumor will reoccur.. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The reasons for this rejection are of record in the paper mailed 4/24/06.

Applicant argues that the amendment to limit "subject" to --human-- and the arguments that Takamizawa et al does that differences in mRNA expression of PAF factor Fas translate into differences in actual Fas protein expression and this is correlated to kidney tumors overcomes the rejection. While the limitation of mammal to human overcomes part of the rejection, the showing in Takamizawa et al does not overcome the rest of the rejection. This reference merely shows that Fas is expressed in kidney tumors. Applicant's claims are not limited to kidney tumors and applicant's claims are not limited to Fas. As discussed in the rejection, mRNA levels of p53 and

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protein levels do not correlate. Thus, what is shown for one PAF does not necessarily apply to all PAF.

***Allowable Subject Matter***

Claim 6 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J. Huff whose telephone number is 571-272-0834. The examiner can normally be reached on Monday, Tuesday and Thursday from 7am to 1pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Sheela J Huff  
Primary Examiner  
Art Unit 1643

sjh